AMENDMENTS TO THE SPECIFICATION

Please replace the paragraphs beginning on page 15, line 21, through page 16, line 22, with the following:

With reference to Figure 2, the lungs include a right lung 210 and a left lung 215. The right lung 210 includes lung regions comprised of three lobes, including a right upper lobe 230, a right middle lobe 235, and a right lower lobe 240. The lobes 230, 235, 240 are separated by two interlobar fissures, including a right oblique fissure 226 and a right transverse fissure 228. The right oblique fissure 226 separates the right lower lobe 240 from the right upper lobe 230 and from the right middle lobe [[135]] 235. The right transverse fissure 228 separates the right upper lobe 230 from the right middle lobe 135.

As shown in Figure 2, the left lung 215 includes lung regions comprised of two lobes, including the left upper lobe 250 and the left lower lobe 255. An interlobar fissure comprised of a left oblique fissure 245 of the left lung 215 separates the left upper lobe 250 from the left lower lobe 255. The lobes 230, [[135]] 235, 240, 250, 255 are directly supplied air via respective lobar bronchi, as described in detail below.

Figure 3A is a lateral view of the right lung 210. The right lung 210 is subdivided into lung regions comprised of a plurality of bronchopulmonary segments. Each bronchopulmonary segment is directly supplied air by a corresponding segmental tertiary bronchus, as described below. The bronchopulmonary segments of the right lung 210 include a right apical segment 310, a right posterior segment 320, and a right anterior segment 330, all of which are

disposed in the right upper lobe 230. The right lung bronchopulmonary segments further include a right lateral segment 340 and a right medial segment 350, which are disposed in the right middle lobe [[135]] 235. The right lower lobe 240 includes bronchopulmonary segments comprised of a right superior segment 360, a right medial basal segment (which cannot be seen from the lateral view and is not shown in Figure 3A), a right anterior basal segment 380, a right lateral basal segment 390, and a right posterior basal segment 395.

Please replace the paragraph on page 24, lines 9-19, with the following:

With reference again to Figure 6B, the valve member 612 is concentrically contained within the seal member 615. In addition, at least a portion of the valve member 612 is optionally surrounded by a rigid or semi-rigid valve protector member 637 (shown in Figures 5B and 6B), which is a tubular member or annular wall that is contained inside the seal member [[622]] 615. In another embodiment, the valve protector can comprise a coil of wire or a ring of wire that provides some level of structural support to the flow control device. The valve protector 637 can be concentrically located within the seal member 615. Alternately, the valve member 612 can be completely molded within the seal member 615 such that the material of the seal member 615 completely surrounds the valve protector.

Please replace the paragraph on page 28, lines 3-9, with the following:

As shown in Figure 8, the frame 625 grips the interior wall 915 and presses against the wall 915 with a pressure sufficient to retain the flow control device 110 in a fixed position relative to the bronchial passageway . The prongs 627 are positioned such that they lodge against the interior walls 915 and prevent the flow

control device 110 from migrating in a distal direction 206. The curved, ~~distal~~ proximal ends 629 of the frame 625 can lodge against the interior walls 915 and prevent migration of the flow control device 110 in a proximal direction 204.

Please replace the paragraph on page 38, lines 9-22, with the following:

Figure 18 shows an alternate embodiment of the flow control device 110 mounted in a bronchial passageway. This embodiment of the flow control device 110 is identical to that described above with reference to Figures 9-11, with the exception of the configuration of the septum 630 and the slit 635. A distal face of the septum has a taper 1510 located at the slit 635. The taper 1510 functions to reduce the cracking pressure required to open slit 635 so that the cracking pressure of the septum 630 will be lower for flow moving from the distal side 1302 toward the proximal side 1301 of the flow control device 110, and higher for flow from the proximal side [[1510]] 1301 to the distal side [[1520]] 1302. The cracking pressure can be made the same in both directions by eliminating the taper 1510. The cracking pressure can be varied by changing the durometer of the elastomer, by changing the diameter of the valve, by changing the length of the slit 635, by changing the angle, depth or shape of the taper feature 1510, or by changing the thickness of the valve feature.

Please replace the paragraphs beginning on page 42, line 24, through page 43, line 9, with the following:

The flow control device 110 is shown in Figure 24 with an optional feature comprised of a valve protector sleeve 1938 that at least partially surrounds the valve dilation member [[1935]] 1930. The valve protector sleeve 1938 can be attached to

the seal member 615 and can made of a biocompatible materials such as stainless steel, Nitinol, etc. In order to ensure that the cracking pressure in the distal direction is not affected by the addition of the valve dilation member 1930, the protector sleeve 1938 preferably has one or more vent holes 1940, which ensure that the pressure is the same on interior and exterior surfaces of the valve dilation member 1930, as well as on the proximal surface of the duckbill valve 1910. In this way, the cracking pressure in the proximal direction is also unaffected.

Please replace the paragraphs beginning on page 49, line 10, through page 50, line 2, with the following:

With reference still to Figure 32, a housing 2940 is located at or near a distal end of the catheter 2915. The housing 2940 is attached to a distal end of the outer member 2918 of the catheter 2915 but not attached to the inner member 2920. As described in more detail below, the housing 2940 defines an inner cavity that is sized to receive the flow control device 110 therein. Figure 33 shows an enlarged, perspective view of the portion of the distal portion of the catheter 2915 where the housing 2940 is located. Figure 34 shows a plan, side view of the distal portion of the catheter 2915 where the housing 2940 is located. As shown in Figures 33 and 34, the housing 2940 is cylindrically-shaped and is open at a distal end and closed at a proximal end. The inner member 2920 of the catheter [[2015]] 2915 protrudes through the housing and can be slidably moved relative to the housing 2940. An ejection member, such as a flange 3015, is located at a distal end of the inner member 2920. As described below, the ejection member can be used to eject the flow control device 110 from the housing 2940. The flange 3015 is sized such that it

can be received into the housing 2940. The housing can be manufactured of a rigid material, such as steel.

Please replace the paragraph on page 51, lines 10-23, with the following:

The delivery catheter 2915 could be modified to add a steerable distal tip function, such as by adding a "pull" wire located inside a new lumen in the outer member 2918 of the delivery catheter 2915. The proximal end of the pull wire would be attached to a movable control that allows tension to be applied to the wire. The distal end of the wire would be terminated at a retainer attached to the distal end of the outer member 2918 of the catheter [[1915]] 2915. The distal portion of the catheter [[1915]] 2915 could be manufactured to be much more flexible than the rest of the catheter 2915, thus allowing the distal end of the catheter 2915 to bend more easily than the rest of the catheter 2915. This distal portion could also have some elastic restoring force so that it will return on its own to a straight configuration after the tip is deflected or the shape of the tip is disturbed. When the moveable control is actuated, thus applying tension to the pull wire, the distal tip or distal portion of the catheter 2915 will deflect. In addition, other ways of constructing steering tips for this delivery catheter could be used.

Please replace the paragraph on page 58, lines 9-22, with the following:

With reference still to Figure 41, after the catheter 2915 is mated with the loader device [[3615]] 3515, the flow control device 110 is positioned adjacent the front opening 3615 of the loading region 3622 of the loader device 3515. As shown in Figure 41, the front opening 3615 is sufficiently large to receive the flow control device 110 therein without having to compress the size of the flow control device

110. Alternately, a slight compression of the flow control device 110 can be required to insert the flow control device 110 into the opening 3615. The pusher device 3520 is then positioned such that an end 3810 of the piston 3710 is located adjacent to the flow control device 110. The housing 2940, flow control device 110 and the piston 3710 are preferably all axially aligned to a common longitudinal axis 3711 prior to loading the flow control device 110 into the housing 2940. However, even if these components are not all axially aligned, the structure of the loader device 3515 will ensure that the components properly align during the loading process.

Please replace the paragraph on page 59, lines 10-17, with the following:

As shown in Figure 43, as the flow control device is pushed toward the housing 2940, the flow control device 110 will eventually be compressed to a size that permits the flow control device to be pushed into the housing 2940. In one embodiment, the loading region 3622 of the loading tunnel 3610 reduces to a size that is smaller than the opening of the housing 2940 so that the flow control device 110 can slide easily into the housing 2940 without any snags. Alternately, the opening in the housing 2940 can be substantially equal to the smallest size of the loading region [[3625]] 3622.

Please replace the paragraph beginning on page 60, line 23, through page 61, line 14, with the following:

Figure 46 shows a rear view of the loader device 3515 with the door 3645 in a default, closed state. When in the closed state, the door partially occludes the opening [[4235]] 4230. The entry port [[4230]] 4235 includes a catheter region 4310 that is sized to receive the outer member 2918 of the catheter 2915. The catheter

region 4310 is aligned with a central axis A of the opening 4230 in the loader device 3515 when the door 3645 is closed. As shown in Figure 47, the door 3645 can be moved to an open position by rotating the door 3645 about an axis defined by the first pin 4210. When the door is in the open position, the entry port 4230 is positioned such that a large portion of the entry port [[4230]] 4235 is aligned with the opening [[4235]] 4230 in the loader device 3515 so that the opening 4230 is unblocked. This allows the housing 2940 of the catheter 2915 to be inserted into the housing region 3630 through the aligned entry port [[4230]] 4235 and opening [[4235]] 4230 while the door 3645 is in the open position, as shown in Figure 48A. The door 3645 can then be released and returned to the closed position, such that the door 3645 partially blocks the opening 4230 and thereby retains the housing 2940 within the housing region 3630, as shown in Figure 48B. The door 3645 can be spring-loaded so that it is biased toward the closed position.

Please replace the paragraph on page 64, lines 13-22, with the following:

The compression mechanism 5530 defines a loading tunnel 5540 that extends through the loader head 5525. The cams 5549 have opposed surfaces that define the shape of the loading tunnel 5540. In the illustrated embodiment, there are four cams [[550]] 5549 that define a rectangular-shaped tunnel looking through the tunnel when the device in the open state. As described below, when the handles 5515, 5520 are closed, the cams 5549 reposition so that the loading tunnel takes on a circular or cylindrical shape, as shown in Figure [[58]] 57. In the open state, the loading tunnel 5540 can accept an uncompressed flow control device 110

that has a diameter D. In alternative embodiments, the compression mechanism 5530 may contain three, five or more cams 5549.

Please replace the paragraph on page 70, lines 3-10, with the following:

Figure 60B shows one embodiment of the foldable sections 7160 in the enlarged view 7161. In this embodiment, the foldable section 7160 includes a single fold and a radial edge [[7163]] of the segment 7150 is positioned to overlap with the adjacent segment 7150. The radial edge 7163 can be free to slide over the adjacent segment 7150 or it can be attached to the adjacent segment. In another embodiment, shown in the view 7165 of Figure 60B, the foldable section 7160 includes two or more folds and the segment 7150 is integrally attached to an adjacent segment 7150.

Please replace the paragraph on page 78, lines 13-22, with the following:

As shown in Figures [[66]] 66A and [[67]] 66B , the frame 8100 has eight membrane struts 8100, but it can have two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, or more struts 8100. The struts shown in the figures are plain end wires, however other configurations may be used. The membrane struts 8150 and the retention struts 8175 (or retention coil 8180) can be made of nickel-titanium alloy (such as Nitinol) wire. Nitinol can be chosen for its super-elastic properties so that the flow control device 8000 can be compressed to a small diameter for insertion in a delivery catheter, yet still expand to its original shape after deployment. It should be appreciated that many other elastic materials would work well including stainless steel, plastic, etc.

Please replace the paragraphs beginning on page 83, line 14, through page 84, line 19, with the following:

In step (d), the delivery catheter is inserted into the bronchial passageway so that the flow control device 110 is positioned at a desired location in the bronchial passageway. This can be accomplished by inserting the distal end of the delivery catheter 2915 into the patient's mouth or nose, through the trachea, and down to the target location in the bronchial passageway. The delivery of the delivery catheter 2915 to the bronchial passageway can be accomplished in a variety of manners. In one embodiment, a bronchoscope is used to deliver the delivery catheter 2915. For example, with reference to Figure [[59]] 71, the delivery catheter 2915 can be deployed using a bronchoscope 5210, which in an exemplary embodiment has a steering mechanism 5215, a shaft 5220, a working channel entry port 5225, and a visualization eyepiece 5230. The bronchoscope 5210 has been passed into a patient's trachea 225 and guided into the right primary bronchus 510 according to well-known methods.

It is important to note that the distal end of the bronchoscope is preferably deployed to a location that is at least one bronchial branch proximal to the target bronchial lumen where the flow control device will be implanted. If the distal end of the bronchoscope is inserted into the target bronchial lumen, it is impossible to properly visualize and control the deployment of the flow control device in the target bronchial lumen. For example, if the bronchoscope is advance into the right primary bronchus 510 as shown in Figure [[59]] 71, the right upper lobar bronchi 517 can be visualized through the visualization eyepiece of the bronchoscope. The right upper

lobar bronchi 517 is selected as the target location for placement of a flow control device 110 and the distal end of the bronchoscope is positioned one bronchial generation proximal of the bronchial passageway for the target location. Thus, the distal end of the bronchoscope is deployed in the right primary bronchus 510. The delivery catheter 2915 is then deployed down a working channel (not shown) of the bronchoscope shaft 5220 and the distal end 5222 of the catheter 2915 is guided out of the distal tip of the bronchoscope and advanced distally until the delivery system housing containing the compressed flow control device is located inside the lobar bronchi 517.

Please replace the paragraphs beginning on page 85, line 15, through page 86, line 13, with the following:

Figure [[60]] 72 illustrates a first step in the process of deploying a delivery catheter 2915 to a target location using a guidewire. A guidewire 5310 is shown passed down the trachea 225 so that the distal end of the guidewire 5310 is at or near the target location 5315 of the bronchial passageway. The guidewire 5310 can be deployed into the trachea and bronchial passageway through free wiring, wherein the guidewire 5310 with a steerable tip is alternately rotated and advanced toward the desired location. Exchange wiring can also be used, wherein the guidewire 5310 is advanced down the working channel of a bronchoscope that has been previously deployed. The bronchoscope can then be removed once the guidewire is at the desired location.

In any event, after the guidewire 5310 is deployed, the distal end of the delivery catheter 2915 is back loaded over the proximal end of the guidewire 5310.

The delivery catheter 2915 is advanced along the guidewire 5310 until the housing 2940 on the distal end of the delivery catheter 2915 is located at the target location 5315 of the bronchial passageway. The guidewire 5310 serves to control the path of the catheter 2915, which tracks over the guidewire 5310, and insures that the delivery catheter 2915 properly negotiates the path to the target site. Fluoroscopy can be helpful in visualizing and insuring that the guidewire 5310 is not dislodged while the delivery catheter is advanced. As shown in Figure [[61]] 73, the delivery catheter 2915 has been advanced distally over the guidewire 5310 such that the housing 2940 at the distal end of the delivery catheter 5310 has been located at the target location 5315 of the bronchial passageway. The flow control device 110 is now ready for deployment.

Please replace the paragraph on page 89, lines 12-19, with the following:

(3) ~~Antiinflammatory~~ Anti-inflammatory agents to reduce inflammation.

(4) Anti-proliferative agents to treat cancer.

(5) Mucolytic agents to reduce or eliminate mucus production.

(6) Analgesics or pain killers, such as Lidocane, to suppress early cough reflex due to irritation.

(7) Coagulation enhancing agents to stop bleeding.

(8) Vasoconstrictive agents, such as epinephrine, to stop bleeding.

(9) Agents to regenerate lung tissue such as ~~all-trans-retinoic~~ all trans-retinoic acid.

Please replace the paragraphs beginning on page 95, line 16, through page 96, line 6, with the following:

In order to ease the navigation of the housing past carinae and into the ostium of a target bronchus, the tip region 3020 of the catheter inner member 2920 can have a rib or elongate protrusion 5810 extending in one direction radially so as to provide the tip region 3020 with an asymmetric shape, such as is shown in Figures [[62]] 74 and [[63]] 75. The tip region 3020 is asymmetric with respect to a central longitudinal axis 6210 of the catheter 2915. The protrusion 5810 can extend radially, for example, as far as the outer diameter of the housing 2940. The protrusion 5810 extends only in one direction in order to minimize the perimeter of the tip region 3020, which facilitates passing the tip region 3020 through the central lumen of the flow control device 110. The protrusion 5810 can be made of a solid material (such as shown in Figure [[62]] 74) or, alternately, the protrusion 5810 can be hollow (such as shown by reference numeral 6310 in Figure [[63]] 75) in order to allow some compressive compliance. The compliance would be such that the protrusion 5810 does not compress when pushed against lung tissue but would compress when it is pulled through the flow control device 110 or pushed into the lumen of a loading device.

Please replace the paragraphs beginning on page 96, line 15, through page 97, line 4, with the following:

As mentioned, the outer shaft 2918 of the delivery catheter 2915 could be shaped to contain a curve, biasing the whole catheter in one direction. In one embodiment, shown in Figure [[64]] 76, the curve 6010, if present, is contained

within a single plane and is limited to a portion, such as 3 inches, of catheter length just proximal to the housing 2940. The plane of the outer shaft curve could be coincident with the plane containing the protrusion 5810 on the tip region 3020. In this manner, the curve in the outer shaft could be used to align the delivery catheter 2915 so that as the catheter 2915 is traveling over a curved guidewire it will have the protrusion 5810 always facing outward relative to the curve. Due to the three dimensional nature of the bronchial tree in the lungs, a useful geometry of the shaped end of the catheter may be a complex curve that bends in three dimension to match the lung anatomy, rather than being a simple curve in single plane (two dimensions). In addition, the proximal end of the catheter 2915 might be shaped to conform to the curve commonly found in endotracheal tubes to ease delivery if the patient is under general anesthesia and is being ventilated.